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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT PAPER NUMBER

1616

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/615,546

Applicant(s)

MILLER ET AL.

Examiner

Alton N. Pryor

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 9-15 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 9-15, 17-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

I. Rejection of claims 9-15,17-26 under 35 USC 103(a) over Stenzler or Hole in view of Cantwell in light of response filed 3/13/06 will not be maintained. Applicant is correct in that the combination of references would result in a toxic substance, nitrogen dioxide.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9,11,12,17-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Level of ordinary skill in the art.

See below:

1) Nature of the invention.

The nature of the invention is to a method of promoting wound healing by applying agent(s) to the wound prior to or after applying nitric oxide to the wound.

2) State of the prior art and the predictability or lack thereof in the art.

The state of the prior art is that it involves screening *in vitro* and *in vivo* to determine which agents (drugs) promote wound healing. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen (agents) on its face. The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Further, their mode of action is often unknown or very unpredictable and administration of the agents (drugs) can be accompanied by undesirable side effects.

Thus, in the absence of a showing of correlation between wound healing and agents claimed as being capable of promoting wound healing, one of ordinary skill in the art is unable to fully predict possible results from the administration of the agents

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due to the unpredictability of the role of the huge number of agents set forth in the claims / specification.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The quantity of experimentation needed is undue experimentation. One of ordinary skill in the art would need to determine which agents would be suitable for promoting wound healing.

5) Amount of direction and guidance provided by the inventor.

Applicant provides no guidance in terms of how the agents would effect wound healing before or after nitric oxide treatment.

6) Existence of working examples.

Applicant provides no working examples of using claimed agents to promote wound healing.

7) Breadth of claims.

Claims are extremely broad due to the vast number of agents encompassed by the instant invention.

8) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. Due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which agents exhibit the desired pharmacological activity, i.e. wound healing.

Hence, the specification fails to provide sufficient support of the use of the agents of the claims for promoting wound healing. As a result necessitating one of ordinary skill in the art to perform an exhaustive search to determine which agents promote wound healing in order to practice the claimed invention.

Genentec Inc. V. Novo Nordisk A/S (CAFC) 42 USPQ 2D 1001, states that:

“a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation to test which agents would promote wound healing, with no assurance of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10,13-15,23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stenzler on record. Stenzler teaches a method of promoting healing of a wound comprising topically applying to the damaged tissue (wound) which is surrounded by an air impermeable cover (bathing unit) an effective amount of gaseous nitric oxide (wound healing agent) and nitrogen (inert agent that enhances local amount nitric oxide delivered to wound). The nitric oxide is applied from a pressurized cylinder which suggests a spray application method. Stenzler teaches that nitrogen prevents the nitric oxide from converting to NO₂. See abstract, column 4 lines 1-47. The method

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promotes the healing of infections incurred by bacteria (pathological process). See column 3 lines 17-25. Stenzler employs a nitric oxide concentration ranging from about 100 to around 1200 ppm in the method. See column 3 line 46 – column 4 line 24.

Stenzler teaches the exposure of wound to nitric oxide for an average of 8 hours. See column 2 lines 7-22. Stenzler does not teach a method of employing 20-1000 ppm gaseous nitric acid. It would have been obvious to one having ordinary skill in the art to employ the instant ppm amount of gaseous nitric acid since the prior art and instant invention ppm amounts of gaseous nitric overlap. With respect to the time of exposure, one having ordinary skill in the art would have determined the optimum exposure time. One would have been motivated to do this in order to promote effective wound healing.

Claims 9-15,17-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hole on record. Hole teaches a method of promoting healing of a wound comprising topically applying to the damaged tissue (wound) which is surrounded by an air impermeable cover (envelope) an effective amount of gaseous nitric oxide (wound healing agent) and nitrogen (inert agent that enhances local amount nitric oxide delivered to wound). The nitric oxide is applied from a pressurized cylinder which suggests a spray application method. Hole teaches that nitrogen prevents the nitric oxide from converting to NO₂. See abstract, paragraph 36. The method promotes the healing of infections incurred by bacteria (pathological process). See paragraph 9. Hole employs a nitric oxide concentration ranging from about 100 to around 1000 ppm in the method. See paragraphs 42-43. Hole teaches the exposure of wound to nitric oxide for an average of 8 hours. See paragraph 10. Hole does not teach a method employing 20-

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1000 ppm gaseous nitric acid. It would have been obvious to one having ordinary skill in the art to employ the instant ppm amount of gaseous nitric acid since the prior art and instant invention ppm amounts of gaseous nitric overlap.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alton Pryor
Primary Examiner
AU 1616